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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,814

10/03/2005

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535 7590 11/01/2007  
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EXAMINER

MCDOWELL, SUZANNE E

ART UNIT

PAPER NUMBER

1791

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DELIVERY MODE

11/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/529,814	Applicant(s) JANSEN ET AL.	
	Examiner Suzanne E. McDowell	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II, claims 2-10 in the reply filed on 8/6/07 is acknowledged. The traversal is on the ground(s) that unity of invention allows claims to a product and process to be examined together. This is not found persuasive because, in order for there to be unity, the process "must be specially adapted for the manufacture of the product". See MPEP §1850 IIIA. In the instant claims, there is no special adaptation in the process which would render the product claim to be examinable with the process. The product and process do not share a special technical feature, as outlined in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 1 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/6/07.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP §

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2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation between 30% and 150%, and the claim also recites between 60 and 125% which is the narrower statement of the range/limitation.

Further regarding claim 2, and claims 5, 6 and 10, (previously presented) in the body of the claims is improper and confusing. Also improper is "[[s]]" in line 2 of claim 2.

Additionally, in claim 3, line 2, "the pore size" and "the extended dimension" do not have antecedent basis. In claim 5, line 7, "the outer side" does not have antecedent basis.

Finally, in claim 10, "polycarbonate type" and "polysulfone type" render the claim indefinite. The meaning of "type" is not clear.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Sridharan et al. (US Patent 6,743,388). Sridharan et al. discloses a method of making a product which may be a vascular prosthesis (column 1, lines 27-30), and is formed by stretching an ultra-high molecular weight polyethylene polymer (UHMWPE) to form a node and fibril structure (column 3, lines 50-53), where the stretch ratio is from about 2:1 to about 20:1 (column 4, lines 24-26).

*Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sridharan et al. (US Patent 6,743,388). Sridharan et al. discloses a method of making a product which may be a vascular prosthesis (column 1, lines 27-30), and is formed by stretching an ultra-high molecular weight polyethylene polymer to form a node and fibril structure (column 3, lines 50-53), where the stretch ratio is from about 2:1 to about 20:1 (column 4, lines 24-26). Regarding claim 3, Sridharan et al. teaches that the stretching determines the porosity of the article formed (column 4, lines 23-25). Therefore, it would be obvious to a person of ordinary skill in the art at the time of the invention to use routine experimentation to determine a stretch ratio which results in the desired pore size. Modifying the stretch ratio taught by Sridharan et al. would result in a pore size that encompasses that claimed.

Regarding claim 4, Sridharan et al. does not specify that the stretching is either uniaxial or biaxial. It is generally well known in the art to stretch uniaxially or, in the alternative biaxially. Either well known method of stretching could be used to further define the method taught by Sridharan et al.

Regarding claims 5, Sridharan et al. contemplates forming a drug reservoir for releasing drugs from transdermal patches (column 1, lines 53-56). It is generally well known in the art that one such method of loading the drug is by soaking. It would have been obvious to a person of ordinary skill in the art at the time of the invention to form the drug reservoir taught by Sridharan et al. by using generally well known techniques, such as soaking, in order to load the product with a desired substance.

Regarding claims 6-9, Sridharan et al. does not teach the claimed methods of molding by expansion. It is generally well known in the art to mold such items as balloons, which are taught by Sridharan et al., by pressurizing with air, with or without a mandrel or core inserted therein. Additionally, it is generally well known in the art to form multilayered articles by expansion. It would have been obvious to a person of ordinary skill in the art at the time of the invention to use generally well known molding techniques, such as pressurizing with air, to further define the methods taught by Sridharan et al. in order to quickly and efficiently form a finished product that is hollow.

Regarding claim 10, Sridharan et al. does not specifically teach that the UHMWPE is recovered by the claimed process. It is generally well known in the art to form UHMWPE by a polymerization and recovery process as in the instant claims. It would have been obvious to a person of ordinary skill in the art at the time of the invention to use a generally well known method of producing the UHMWPE to produce the polymer as taught by Sridharan et al. depending upon material characteristics, cost, availability, etc.

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*Conclusion*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Szycher et al. (US Patent 5,254,662); and Herweck et al. (US Patent 5,197,976).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne E. McDowell whose telephone number is (571) 272-1205. The examiner can normally be reached on Mon and Fri 5:30am-2pm, Tues 10am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Suzanne E. McDowell  
Primary Examiner  
Art Unit 1791

10/29/07

SEM  
October 29, 2007